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August 11, 2004

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane Room 1061
Rockville, MD 20852

RE: Docket No. 2004N-0264

The National Cattlemen's Beef Association (NCBA) has carefully reviewed the Advanced Notice of Proposed Rule-Making (Docket No. 2004N-0264) announced on July 9th and published in the Federal Register on July 14, 2004. In addition, the NCBA joined over 10 other organization in asking the Food and Drug Administration (FDA) for an additional 60 days to comment on this extensive set of questions as this is a task of great scope, significance and complexity.

The National Cattlemen's Beef Association (NCBA) is the largest organization representing America's cattle industry. Initiated in 1898, the NCBA is the industry leader in providing education and in influencing the development and implementation of science and risk analysis-based public policy to protect the health of the U.S. cattle population, provide safe and wholesome food and improve producer profitability. In this regard, the NCBA also strives to preserve the industry's heritage and ensure our future.

We appreciate this opportunity to share with the FDA our perspectives on the proposals designed to evaluate the need for, benefits of and implications for taking additional actions to prevent the amplification and spread of Bovine Spongiform Encephalopathy (BSE) in the United States.

As indicated by the FDA, the extensive list of questions in the ANPRM are designed to surface and define both the scientific basis for additional BSE prevention measures, the risk reduction impacts and implication for the industry and the environment. Specifically the FDA requests comments and scientific information on several additional measures related to animal feed under consideration to help prevent the spread of BSE in the United States. Some of these measures include:

- removing specified risk materials (SRMs) from all animal feed, including pet food, in order to control the risks of cross contamination throughout feed manufacture and distribution and on the farm due to misfeeding;
- requiring dedicated equipment or facilities for handling and storing feed and feed ingredients during manufacturing and transportation, to prevent cross contamination;

2004N-0264 C57

- prohibiting the use of all mammalian and poultry protein in ruminant feed, to prevent cross contamination; and
- prohibiting materials from non-ambulatory disabled cattle and dead stock from use in all animal feed.

It is important to mention that the NCBA is very concerned that the FDA "has tentatively concluded that it should propose to remove SRMs from all animal feed and is currently working on a proposal to accomplish this goal." The core of our comments will challenge this assumption as it does not appear to be grounded in evidence, science, nor risk analysis.

For the reasons we detail in our comments, we do not believe that the current risk analysis data, coupled with an over 15 year history of proactive BSE prevention measures supports the FDA concluding that the SRM and other measures discussed in the ANPRM are necessary at this time.

It seems the FDA is responding to a statement made in the International Review Teams (IRT) report "While the science would support the feed bans limited to the prohibition of ruminant derived [meat and bone meal] MBM in ruminant feed, practical difficulties of enforcement demand more pragmatic and effective solutions." The IRT implied that this conclusion is based upon epidemiological evidence from the United Kingdom.

The fact is, decisions made to identify, control and eradicate diseases such as BSE can not be based upon the disease prevalence, feeding practices, regulations and other measures taken in the UK and then applied unilaterally to the situation in the U.S. Such an opinion of the IRT literally ignores the actions taken by the U.S. since 1989, 14 years of BSE surveillance data, existing FDA feed ban compliance data and a comprehensive risk analysis conducted by the Harvard School of Public Health Center for Risk Analysis.

We want to take this opportunity to summarize all of these elements that must go into the decision-making process, information apparently ignored or dismissed by the IRT.

Risk Analysis and Reduction Measures Taken in the U.S. since 1989

The primary risk of BSE introduction into the United States relates to the importation of cattle from the United Kingdom (UK) prior to 1989. APHIS records indicated they conducted a trace back effort to locate each of the 496 UK and Irish cattle that were imported into this country between January 1, 1981, and July 1989. In 1996, personal communications with APHIS staff indicated that few of these animals came from farms in the UK that had cases of BSE. Thus the risk of these imported cattle were exposed to BSE was analyzed to be low. At the same time, it was estimated that perhaps as few as 2 of these imported animals might present a BSE risk. An effort was made in 1996 and 1997 to depopulate all remaining UK cattle and to test them for BSE. None of these animals were found to have BSE as a result of this testing program. The USDA also traced the location of any other cattle imported into the U.S., from other countries that subsequently had cases of BSE. Five head of cattle imported from other countries in

Europe in 1996–97 remain were place under quarantine and eventually were depopulated and tested. None were found to have BSE.

In December 1997, the USDA expanded the list of countries identified as having or at risk of BSE including the virtually all of Europe.

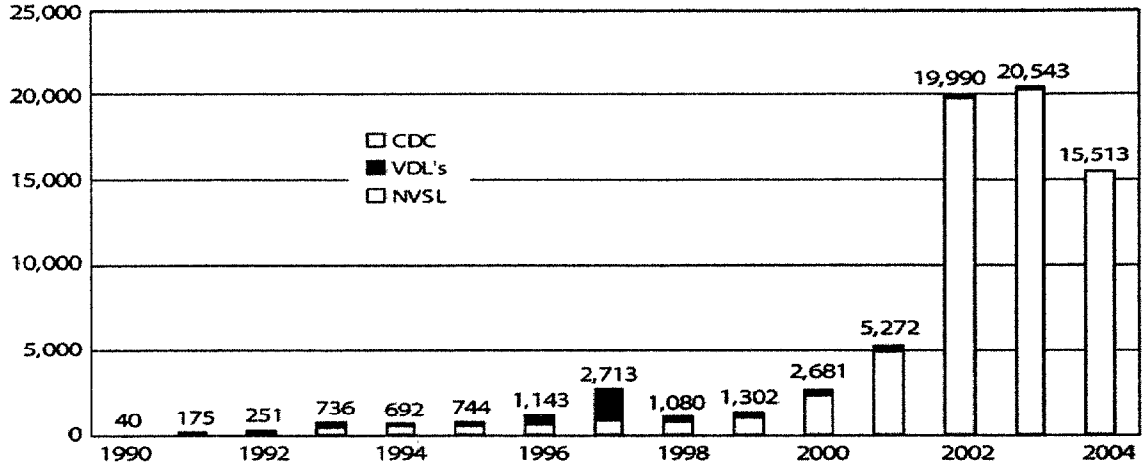
In 1990 a BSE surveillance program was implemented in the U.S., initially using samples of brain tissue provided from rabies suspect cattle. The population of rabies suspect cattle over 30 months of age continues to be an important contributor of samples for the BSE Surveillance program.

The BSE surveillance program in the United States exceeded the minimum standards for BSE surveillance set by the International Office of Epizootics which estimated the U.S. need only sample between 400-500 animals to provide a valid estimate of BSE prevalence. In 1999 an effort was made to increase the surveillance program in order to provide a higher level of confidence in our assumptions that even if the BSE agent had been introduced into the U.S. the prevalence of the disease was very low and the FDA feed bans put in place in 1997 would effectively be reducing the risk of amplification and spread.

An assumption was made to design a surveillance program capable of identifying the disease if it existed at a level of 1/million cattle over 30 months of age. Assuming most of these cattle would be in the population of cattle that were disabled, diseased or dead, it was assumed that 45 cases of BSE (1/million, with 45 million cattle over 30 months of age) would be found in a population of 195,000 cattle as estimated by a survey conducted by the American Association of Bovine Practitioners. The USDA applied Cannon and Roe's formula to determine the sample size needed to be tested to detect disease at the estimated prevalence indicating that, nationally, a sample size of 12,500 was needed.

USDA data illustrate that in 2002, 2003 and until June of 2004 an average of nearly 20,000 cattle in the higher risk, targeted population had been sampled.

BSE Surveillance – May 1990 – FY2004 (through 4/30/2004)



(Source USDA Animal and Plant Health Inspection Service)

On June 1, 2004, the BSE surveillance program shifted to a large, one time sampling of over 200,000 cattle in the higher risk, targeted population as recommend by the IRT. As of July 25, 2004 more than 23,600 additional samples had been collected as illustrated in the following USDA summary as of August 2, 2004.

Table 1 BSE Test Results: Cumulative Total from June 1, 2004: 28,254

Date	Negative	Inconclusive	Inconclusive Result	Positive	Total*
Week 9 (7/26-8/1)	4,414	0	–	0	4,414
Week 8 (7/19-7/25)	4,086	0	–	0	4,086
Week 7 (7/12-7/18)	3,872	0	–	0	3,872
Week 6 (7/5 - 7/11)	3,463	0	–	0	3,463
Week 5 (6/28 -7/4)	3,503	1	Negative	0	3,504
Week 4 (6/21-6/27)	3,258	1	Negative	0	3,259
Week 3 (6/14-6/20)	2,671	0	–	0	2,671
Week 2 (6/7-6/13)	1,840	0	–	0	1,840
Week 1 (6/1-6/6)	1,145	0	–	0	1,145

Since 1990 the U.S. targeted surveillance program has sampled more than 90,000 animals and has never identified a domestic case of BSE. This provides us confidence that if the disease is present at all, it is at a very low prevalence. This is important as this is one of the critical assumptions within the Harvard Center for Risk Analysis study. In the presence of data indicating the risk of BSE is low in the U.S. it is impossible to understand how the IRT could compare the situation in the U.S. to that of the UK and consequently make recommendations for additional regulatory actions on that basis.

The Harvard Center for Risk Analysis Study Significance

In April of 1998 the USDA contracted with Harvard University Center for Risk Analysis and Tuskegee University to conduct a comprehensive Analysis of the risk of BSE in the United States and the prevention measures that had been put in place.

The project took 3 years to complete and was revised in 2003. The model developed is easily the most comprehensive BSE model ever developed. It created an array of simulations built upon assumptions ranging from the initial prevalence of BSE in the U.S. prior to the 1997 FDA feed ban (1, 5, 10, 20, 50, 200 or 500) coupled with the effect of the FDA feed ban, including an assumption of less than 100 % compliance.

Harvard reports that in every scenario, there is too little BSE infectivity in the U.S. cattle system, coupled with a solid history of FDA feed ban compliance to perpetuate the disease. Harvard determined the U.S. was not only extremely resistant to the disease but if it had been introduced; it was on a steady path of eradication as a result of the fed bans.

In light of this information, we strongly urge the FDA to share with us their analysis of the BSE risks, including any additional analysis conducted by the Harvard Center for Risk Analysis that details the risk/benefits and costs associated with the proposed set of options outlined in the ANPRM.

The FDA Feed Ban Structure and Compliance Data

To prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE) through animal feed in the United States, FDA implemented a final rule that prohibits the use of most mammalian protein in feeds for ruminant animals. This rule, 21 CFR Part 589.2000 of the Code of Federal Regulations, became effective on August 4, 1997. The enforcement of the rule entails inspections of renderers, feed mills, ruminant feeders, protein blenders, pet food manufacturers, pet food salvagers, animal feed distributors and transporters, ruminant feeders and other entities. The FDA has routinely posted all results in a database accessible at:

www.fda.gov/cvm/index/bse/RuminantFeedInspections.htm

Documents posted at the FDA web site illustrate the status of thousands of inspections of facilities that have occurred since the rules were established.

Since the rules went into effect it is clear that the firms have committed to implementing the regulation, and due to re-inspections, there are ever higher levels of compliance at the time of the follow-up inspection. Thus BSE amplification risks have continued to be reduced and no evidence exists that the disease prevalence exceeds the range of options evaluated in the Harvard study. These facts continue to point toward the effectiveness of the U.S. system and refute the need for additional BSE prevention measures to protect cattle health.

It is important to review the FDA's Center for Veterinary Medicine (CVM) compliance data that has been assembled and reported. One means of documenting the high level of compliance and how it has consistently increased over time is to use the data as of June 12, 2001 and compare it to the most current data set as of July 29, 2004.

The CVM reported that by June 12, 2001, they had received inspection reports covering inspections (both initial inspections and re-inspections) of 9,867 different firms. The majority of these inspections (around 80%) were conducted by State officials under contract to FDA and the remainder by FDA officials.

Various segments of the feed industry had different levels of compliance with this feed ban regulation. The results to date are reported here both by "segment of industry" and "in total".

By June 12, 2001 of the 435 licensed feed mills handling prohibited materials, at their most recent inspection (either an initial or a follow-up inspection):

- 47 (11%) had products that were not labeled as required
- 45 (10%) did not have adequate systems to prevent co-mingling
- 8 (2%) did not adequately follow record keeping regulations
- 76 (17%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

FEED MILLS NOT LICENSED BY FDA:

Of the 1,580 feed mills not licensed by FDA which handle prohibited materials, at their most recent inspection (could have been an initial or a follow-up inspection):

- 312 (20%) had products that were not labeled as required
- 169 (11%) did not have adequate systems to prevent co-mingling
- 85 (5%) did not adequately follow record keeping regulations
- 421 (27%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

OTHER FIRMS INSPECTED:

- 84 (14%) had products that were not labeled as required
- 25 (4%) did not have adequate systems to prevent co-mingling
- 29 (5%) did not adequately follow record keeping regulations
- 110 (18%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule)

TOTALS (by June 12, 2001):

Of the 2,653 firms handling prohibited materials, at their most recent inspection (either an initial or a follow-up inspection):

- 431 (16%) had products that were not labeled as required
- 222 (8%) did not have adequate systems to prevent co-mingling
- 112 (4%) did not adequately follow record keeping regulations
- 591 (22%) firms were found to be out of compliance (some firms were out of compliance with more than one aspect of the rule. These 591 firms will be re-inspected in the near future.)

Re-inspections:

When firms are found to be out of compliance with the feed ban rule, FDA lists them for a re-inspection. By June 12, 2001, reports of 1,251 re-inspections have been submitted to CVM. On re-inspection of these 1,251 firms, 106 (8%) were found still to be out of compliance with this rule. **Firms previously found to be not in compliance have corrected problems through a variety of ways, including further training of employees about the rule, developing systems to prevent co-mingling, re-labeling their products properly, and adhering to record keeping regulations. Other firms have achieved compliance by eliminating prohibited materials from their operations.**

FDA 2004 Compliance Data

The FDA's CVM has assembled data from the inspections that have been conducted AND whose final inspection report has been recorded in the FDA's inspection database as of April 17, 2004. As of April 17, 2004, FDA had received over 29,000 inspection reports. The majority of these inspections (around 70%) were conducted by State officials under contract to FDA, with the remainder conducted by FDA officials.

It is important to note that the FDA has clarified the nature of compliance issues to more effectively put in perspective the "risk" posed by a compliance problem identified during an inspection. Some problems are merely a paperwork issue rather than actual violations in the production of feed ingredients or feeding of prohibited materials to cattle.

Inspections conducted by FDA or State investigators are classified to reflect the compliance status at the time of the inspection based upon the objectionable conditions documented. These inspection conclusions are reported as Official Action Indicated (**OAI**), Voluntary Action Indicated (**VAI**), or No Action Indicated (**NAI**).

An **OAI** inspection classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified with OAI violations will be promptly re-inspected following the regulatory sanctions to determine whether adequate corrective actions have been implemented

A **VAI** inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified with VAI violations are more technical violations of the Ruminant Feed Ban. These include provisions such as minor recordkeeping lapses and conditions involving non-ruminant feeds.

An **NAI** inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable

RENDERERS

Of the 159 active firms handling prohibited materials, their most recent inspection revealed that:

0 firms (0%) were classified as OAI; 2 firms (1.3%) were classified as VAI

LICENSED FEED MILLS

FDA licenses these feed mills to produce medicated feed products. The license is required to manufacture and distribute feed using certain potent drug products, usually those requiring some pre-slaughter withdrawal time. This licensing has nothing to do with handling prohibited materials under the feed ban regulation. A medicated feed license from FDA is not required to handle materials prohibited under the Ruminant Feed Ban.

Of the 338 active firms handling prohibited materials, their most recent inspection revealed that:

1 firm (0.3%) was classified as OAI; 7 firms (2.2%) were classified as VAI

FEED MILLS NOT LICENSED BY FDA

These feed mills (approximately 1,000 inspected in conjunction with other FDA actions on farms) are not licensed by the FDA to produce medicated feeds.

6 firms (0.5%) were classified as OAI; 36 firms (3.2%) were classified as VAI

PROTEIN BLENDERS

These firms blend rendered animal protein for the purpose of producing quality feed ingredients that will be used by feed mills.

Of the 67 active firms handling prohibited materials, their most recent inspection revealed that:

1 firm (1.5%) was classified as OAI; 2 firms (3.0%) were classified as VAI

RENDERERS, FEED MILLS, AND PROTEIN BLENDERS

This category includes any firm that is represented by any of the above four categories, but includes only those firms that manufacture, process, or blend animal feed or feed ingredients utilizing prohibited materials.

Of the 542 of active renderers, feed mills, and protein blenders processing with prohibited materials, their most recent inspection revealed that:

7 firms (1.3%) were classified as OAI; 19 firms (3.5%) were classified as VAI

OTHER FIRMS INSPECTED

Examples of such firms include ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters.

- Number of active firms whose initial inspection has been reported to FDA – 10,393

- Number of active firms handling materials prohibited from use in ruminant feed – 1,842 (18% of those active firms inspected)

- Of the 1,842 active firms handling prohibited materials, their most recent inspection revealed that:

  11 firms (0.6%) were classified as OAI; 68 firms (3.7%) were classified as VAI

TOTAL FIRMS

Note that a single firm can be reported under more than one firm category; therefore, the summation of the individual OAI/VAI firm categories will be more than the actual total number of OAI/VAI firms, as presented below.

- Number of active firms whose initial inspection has been reported to FDA – 14,037

- Number of active firms handling materials prohibited from use in ruminant feed – 2,474 (18% of those active firms inspected)

- Of the 2,474 active firms handling prohibited materials, their most recent inspection revealed that:

  11 firms (0.4%) classified as OAI; 80 firms (3.2%) were classified as VAI

On July 29, 2004 the FDA Center for Veterinary Medicine published additional data documenting compliance with the feed ban as of July 17, 2004. As of July 17, 2004 FDA had received over 31,000 inspection reports. The majority of these inspections (around 70%) were conducted by State officials under contract to FDA.

RENDERERS

These firms are the first to handle and process (i.e., render) animal proteins and to send these processed materials to feed mills and/or protein blenders for use as a feed ingredient.

- Number of active firms whose initial inspection has been reported to FDA – 244
- Number of active firms handling materials prohibited from use in ruminant feed – 161 (66% of those active firms inspected)
- Of the 161 active firms handling prohibited materials, their most recent inspection revealed that:
  - 0 firms (0%) classified as OAI; 4 firms (2.5%) were classified as VAI

LICENSED FEED MILLS

FDA licenses these feed mills to produce medicated feed products. The license is required to manufacture and distribute feed using certain potent drug products, usually those requiring some pre-slaughter withdrawal time. This licensing has nothing to do with handling prohibited materials under the feed ban regulation. A medicated feed license from FDA is not required to handle materials prohibited under the Ruminant Feed Ban.

- Number of active firms whose initial inspection has been reported to FDA – 1,081

- Number of active firms handling materials prohibited from use in ruminant feed – 367 (34% of those active firms inspected)
- Of the 367 active firms handling prohibited materials, their most recent inspection revealed that:
    - 3 firms (0.8%) classified as OAI; 5 firms (1.4%) were classified as VAI

FEED MILLS NOT LICENSED BY FDA

These feed mills are not licensed by the FDA to produce medicated feeds.

- Number of active firms whose initial inspection has been reported to FDA – 5,059
- Number of active firms handling materials prohibited from use in ruminant feed – 1,358 (27% of those active firms inspected)
- Of the 1,358 active firms handling prohibited materials, their most recent inspection revealed that:
    - 6 firms (0.4%) classified as OAI; 36 firms (2.7%) were classified as VAI

PROTEIN BLENDERS

These firms blend rendered animal protein for the purpose of producing quality feed ingredients that will be used by feed mills.

- Number of active firms whose initial inspection has been reported to FDA -- 267
- Number of active firms handling materials prohibited from use in ruminant feed -- 67 (25% of those active firms inspected)
- Of the 67 active firms handling prohibited materials, their most recent inspection revealed that:
    - 1 firm (1.5%) classified as OAI; 2 firms (3.0%) were classified as VAI

RENDERERS, FEED MILLS, AND PROTEIN BLENDERS

This category includes any firm that is represented by any of the above four categories, but includes only those firms that manufacture, process, or blend animal feed or feed ingredients utilizing prohibited materials.

- Number of active renderers, feed mills, and protein blenders whose initial inspection has been reported to FDA – 6,452
- Number of active renderers, feed mills, and protein blenders processing with prohibited materials – 556 (8.6% of those active firms inspected)
- Of the 556 of active renderers, feed mills, and protein blenders processing with prohibited materials, their most recent inspection revealed that:
    - 8 firms (1.4%) classified as OAI; 19 firms (3.4%) were classified as VAI

OTHER FIRMS INSPECTED

Examples of such firms include ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters.

- Number of active firms whose initial inspection has been reported to FDA – 10,915
- Number of active firms handling materials prohibited from use in ruminant feed – 2,205 (20% of those active firms inspected)
- Of the 2,205 active firms handling prohibited materials, their most recent inspection revealed that:
    - 16 firms (0.7%) classified as OAI; 76 firms (3.4%) were classified as VAI

TOTAL FIRMS

Note that a single firm can be reported under more than one firm category; therefore, the summation of the individual OAI/VAI firm categories will be more than the actual total number of OAI/VAI firms, as presented below.

- Number of active firms whose initial inspection has been reported to FDA – 14,355
- Number of active firms handling materials prohibited from use in ruminant feed – 2,901 (20% of those active firms inspected)
- Of the 2,901 active firms handling prohibited materials, their most recent inspection revealed that:
    - 17 firms (0.6%) classified as OAI; 86 firms (3.0%) were classified as VAI

The level of compliance demonstrated in these FDA reports is outstanding and well within the range of the set of assumptions utilized by the Harvard Center for Risk Analysis that determined the U.S. is extremely resistant to BSE and if present it is being eradicated as a result of the current feed restrictions. As is evident, the rate of **OAI** inspection violations is extremely low and declining (an OAI violation classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation).

BSE Feed Regulation Team Receives Vice Presidential Award

As additional evidence of the success of the enforcement plan established by the FDA has reported that on May 14, 1999 the Food and Drug Administration (FDA)/Association of American Feed Control Officials (AAFCO) Bovine Spongiform Encephalopathy Feed Regulation Team was honored with Vice President Al Gore's Hammer Award. The BSE Feed Regulation Team is comprised of employees from FDA's Center for Veterinary Medicine (CVM) and Office of Regulatory Affairs (ORA), and AAFCO, an organization that includes officials from all States and the Federal government who are responsible for

enforcing the laws regulating the production, labeling, distribution, and/or sale of animal feeds.

The award citation read, "For making a significant contribution to reducing the possibility of bovine spongiform encephalopathy (BSE, or 'mad cow disease') becoming established and spread in the U.S." The Team used an innovative education-oriented partnership program to enforce a FDA regulation designed to control BSE. Compliance rates for the first inspections of all but one industry segment equaled or exceeded 75 percent. Compliance rates at follow-up inspections should approach the goal of 100 percent compliance, based on the enforcement strategy developed and updated jointly by the partners. Independent research has shown that major industry adjustments have been made to facilitate compliance with the regulations. FDA and State inspectors have conducted an unprecedented number of education-oriented inspections; a reinvented approach to doing inspections that has resulted in 70 percent savings in the cost of inspections, amounting to $1.3 million in Fiscal year 1999. (Source: FDA Website)

Thus, there is an abundance of data to verify that the FDA's 1997 ruminant feed rule has been a critical and effective safeguard to stop the spread of BSE through the U.S. cattle population by prohibiting the feeding of most mammalian protein to cattle and other ruminant animals.

On January 26, 2004 FDA Commissioner Mark B. McClellan, M.D., Ph.D. stated "FDA's vigorous inspection and enforcement program has helped us achieve a compliance rate of more than 99 percent with the feed ban rule, and we intend to increase our enforcement efforts to assure compliance with our enhanced regulations. Finally, we are continuing to assist in the development of new technologies that will help us in the future improve even further these BSE protections. With today's actions, FDA will be doing more than ever before to protect the public against BSE by eliminating additional potential sources of BSE exposure." (Source: FDA website)

Also posted on the FDA website are feed ban enforcement actions. When the FDA has identified a firm in violation of the FDA feed ban, actions have been taken as evidence by the following statement provide by the FDA.

"The Department of Justice, Civil Division, Office of Consumer Litigation and the United States Attorney's Office of the Western District of Washington filed the Consent Decree in the United States District Court of the Western District in Tacoma, Washington. It permanently enjoins X-Cel from manufacturing animal feeds in violation of the Food Drug and Cosmetic Act and requires the firm, its officers, and employees to take specific steps to avoid future violations including, implementing clean-out procedures, obtaining protein supplier certifications and implementing standard operating procedures for compliance until it satisfies FDA that it has corrected its problems."

This is additional evidence that FDA compliance is outstanding and that failures to comply are dealt with aggressively.

Department of Health and Human Services- FDA 2005 Budget Request

The validity of staying on the 100% feed ban compliance course was clearly articulated in the Fiscal 2005 FDA Justification of Estimates for Appropriations Committees.

In this document the FDA outlines its intentions to use the requested budget of over $8 million to "undertake a trilateral approach (to BSE prevention) of increased inspections, enforcement activities and education. These are all areas we fully support and believe will be adequate to prevent the amplification and spread of BSE in the U.S.

International Review Team Report

It is imperative that the FDA base its decisions to add additional regulations to prevent the amplification and spread of BSE on science and risk analysis.

In this regard, there are no data to suggest either the risk of BSE in the United States has changed since the FDA developed the 1997 feed regulations. In addition FDA data on feed ban compliance is exemplary. Thus, our low BSE risk coupled with a high degree of feed ban compliance clearly indicates there is no risk based nor scientific justification to expand the BSE prevention measures to include removal of SRMs or other measures as detailed in the ANPRM.

It appears the sole basis for this ANPRM is the International Review Team (IRT) report. It is important to note that the IRT did not provide a single reference or data set to support their assumptions that additional steps were likely necessary in the U.S. to prevent the amplification and spread of BSE. In fact their assumption that additional actions were warranted based upon "epidemiological evidence in the United Kingdom" is inconsistent with the principles of risk analysis. These principles include that you must analyze risk within the given context of the country and its systems rather than simply extrapolate from existing data and experiences. This is exactly what the Harvard study accomplished.

It actually seems that the IRT predicated its recommendations upon data to be gathered as a result of the large, one time sample of the high risk cattle population that is being carried out at this time. Data from this expanded surveillance program must be used within the context of additional analysis using the Harvard model. This process and data utilization must be the foundation of our decision-making process. If the expanded surveillance program were to alter our BSE prevalence assumptions included in the Harvard BSE Risk Analysis and/or the surveillance program indicates there are cases of BSE born after the feed ban, then and only then would additional BSE prevention measures be appropriate for consideration.

BSE Risk Reduction: Options and Costs

The CVM has documented outstanding compliance with the existing feed bans. The Harvard Center for Risk analysis study clearly indicates that with such compliance and the surveillance program validated low BSE risk in the U.S. if BSE were present it is well on the way to being eradicated. Thus, at this time, there is no scientific or other evidence to support taking steps to reduce the risk of BSE further in the U.S. If our assumptions change, as a result of the expanded surveillance program, the following rationale should be considered as the FDA contemplates an SRM removal based approach to reducing BSE risk in the U.S.

Current BSE Risk Sources: Assumptions

In an effort to analyze the amount of theoretical BSE risk reduction as a result of taking the steps in the ANPRM, we have made the following assumptions that are the foundation of our analysis:

1. 100% of BSE risk is from cattle consumption of Ruminant Derived Meat and Bone Meal in any form or in any feed or ingredient, including cross contamination.

2. If we assume the current level of compliance with the 1997 FDA Feed Restrictions is at least 95% (actual data indicate less than 1.5% of any of the regulated firms handling prohibited ruminant derived meat and bone meal had OAI violations in the last year) what steps could be taken to reduce that risk further and at what cost? In other words what is the impact on the remaining 5% of the risk from the proposed actions (actual risk remaining is likely closer to 1.5% with 98.5% compliance)?

3. We assume the following estimates of the risk of BSE infectivity:

   Dead, dying, disabled (4-D) cattle and those over 30 months failing antemortem inspections contribute at least 82% of the Lethal Doses (LD-50) of BSE in the total cattle population. An LD-50 is the dose that would infect 50% of cattle exposed.

   In animals that pass antemortem inspection, the brain and spinal cord would contain at least 90% of the potential LD-50 doses remaining in the cattle population.

   The tonsil, distal ileum, eyes, and other SRMs would contain no more than 10% of the remaining BSE LD-50 units from the cattle that pass antemortem inspection

   We calculate the cost per unit of risk reduction as the total cost of the proposed action divided by the percentage in risk reduction provided by that step. Our unit of risk reduction is reported as dollars per 1% reduction in total risk.

   BSE risk can be categorized in the following manner based upon assumptions from the Harvard Risk Analysis and other sources:

- Meat and Bone Meal from 4-D Cattle contain 82% of the risk of BSE remaining after 95% compliance with the feed ban. Thus, the total risk reduction achieved by removing meat and bone meal from these cattle from the animal feed supply would be 82% of the remaining 5% risk or 4.1% of total risk

- The brain and spinal cord from animals over 30 months that pass antemortem inspection would represent 90% of the remaining BSE risk in meat and bone meal. This equated to 90% of the 0.9% of remaining risk or 0.8%.

Harvard indicates removal of 4-D cattle from the animal feed production system would reduce risk by 82% of the remaining 5% for a total risk reduction of 4.1%. To view the additive effect of taking out the brain and spinal cord from cattle over 30 months would take 90% of the remaining 0 .9% for a total additional risk reduction of 0 .8% for a total of 4.9%

If in addition you remove all the remaining SRMs from all cattle over 30 months from meat and bone meal you would reduce the risk by the following amount:

Removal of 4-D cattle risk reduction	4.1%
Removal of brain and spinal cord risk reduction	0.8%
Total	4.9%
Remaining risk potentially reduced by removal of all SRMs	0.1%

Another possible BSE risk reduction step would be the removal of all ruminant meat and bone meal from all livestock feed. There are two ways to view this approach; one would be the additive level of risk reduction on top of the 4-D, brain and spinal cord removal steps. In this case the most such a prohibition would provide is a reduction of 0.1%. The other method or means would be to eliminate the feeding of all ruminant meat and bone meal to all animals instead of removing 4-D and/or SRMs. In this scenario, the removal of all ruminant meat and bone meal from all animal might approach the elimination of the full 5% of remaining risk, that risk remaining assuming 95% compliance with the FDA feed ban

The cost to remove all meat and bone meal from 4-D Cattle from all animal feed production is estimated to cost between $64 and $76 million based upon some industry estimates.

- Based upon a risk reduction of 4.1% over existing regulations the Cost/unit of risk reduction: $15.6 to 18.5 million

The cost to remove brain and spinal cord from animals over30 months that pass inspection (6.5 million head/year) is estimated to cost $1.4 to $1.7 million

- **Based upon an estimated reduction in risk of 0.8% the Cost/unit of risk reduction could be estimated at $1.75 to $2.1 million**

In addition to the removal of 4-D cattle and brain and spinal cord, we could also remove all remaining SRMs from all cattle over 30 months from the feed supply and reduce the risk by an additional 0.1 of total remaining risk (the 5% of risk left after existing feed ban compliance).

- Cost to remove from all animal feed production: $130 to $158 million
- **Cost/unit of risk reduction: $1.3 to 1.6 billion**

As an alternative method of BSE risk reduction one could reduce risk through removal all ruminant meat and bone meal from all livestock feed in lieu of SRM or other actions to reduce the risk by 5% of the total would cost $636 million

- Cost/unit of risk reduction: $127.2 million

Table 2: Bovine Spongiform Encephalopathy: Risk, Reduction Options and Costs

Risk Reduction Method	% Risk Reduction	Cost (millions)	Cost/%Unit
FDA Feed Ban (current)	95.0	$75	$0 .79 mil/% pt
Remaining Risk: 5%			
Removal of 4-D, Condemned	4.1	$64-76	$15.6-18.5 mil/% pt
Removal of brain and spinal cord from over 30 month cattle	0.8	$1.4-1.7	$1.75-2.1 mil/% pt
Remove all other SRMs	0.1	$130-158	$1.3-1.58 bil/% pt
Remove all ruminant meat and bone meal from feed supply (no other steps taken)	5.0	$636	$127.2 mil/% pt

Conclusions

- There is virtually no immediate way to get to zero risk, over time, risk will near zero as BSE is eradicated.
- The cost of each incremental percentage of risk reduction rises dramatically as additional SRMs above and beyond brain and spinal cord from animals that pass antemortem inspection and are over 30 months of age
- **The most cost effective and way to prevent BSE is full compliance with the FDA feed restrictions followed by removal of 4-D cattle and antemortem condemned, and brain and spinal cord removal from cattle over 30 months that pass antemortem inspection.**
- Removing 4D animals (or their appropriate SRMs), spinal cord and brain from animals over 30 months removes over 82% of the remaining (5%) BSE risk
- Total risk reduction assuming 95% compliance with the FDA feed restrictions plus 4-D cattle, brain and spinal cord removal from cattle over 30 months that pass antemortem inspection would add up to over 99.8 % risk reduction at an additional cost of approximately $65.4 to $77.7 million.

Thus, even if data from the expanded surveillance program indicates our risk assessment assumptions were underestimated, there is no need for a complete, long list of SRM removal from cattle to reduce BSE risk further. Removal of 4-D animals (or their appropriate SRMs) from the animal feed supply reduces BSE risk the most, followed by removal of brain and spinal cord from animals over 30 months. The remaining risk is virtually non-existent and extremely costly to achieve as measured per unit of risk reduction. Consequently there is certainly no need to consider taking extreme steps to minimize an already small and arguably, progressively smaller risk of BSE transmission in the U.S. based upon all existing data.

FDA Feed Restriction Proposed in January 2004

After a BSE-positive cow was detected in late December 2003, FDA announced its plans to publish interim final rules on BSE that would take effect immediately upon publication. For animal feed, FDA stated that the rule would eliminate the present exemption in the ruminant feed rule that allows mammalian blood and blood products to be fed to other ruminants as a protein source, ban the use of "poultry litter" as a feed ingredient for ruminant animals, and ban the use of "plate waste" as a feed ingredient for ruminants. In addition, FDA said that to further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed, the rule would require equipment, facilities, or production lines to be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed.

The NCBA supports the requirement proposed in January that equipment, facilities, or production lines must be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed.

The NCBA supports a process to determine the risks associated with feeding broiler litter to cattle and FDA action if such an analysis indicates it represents a significant risk of BSE amplification and spread.

The NCBA supports the FDA in conducting a risk analysis of the use of blood and blood products in cattle diets. If data indicate specific products pose an unacceptable risk then we would support prohibiting the use of those specific products. It appears the data does not support a complete prohibition of the use of all blood products to cattle.

The NCBA also support actions taken in January by the USDA to protect public health and also those announced by the FDA on July 9, 2004 that prohibits the use of cattle-derived materials that can carry the BSE-infectious agent in human foods, including certain meat-based products and dietary supplements, and in cosmetics. These high–risk cattle-derived materials include SRMs that are known to harbor concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months of age or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age. Prohibited high-risk bovine materials also include material from non-ambulatory disabled cattle, the small intestine of all cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef. These measures aid in protecting public health and thus leave the discussions contained in the ANPRM as issues related to protecting animal health, but not of direct significance to public health which is fully protected through other, direct means.

Specific ANPRM Questions and Responses

3. What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm? What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material?

- In consultation with our members and the feed industry they indicate that they do not have data of this type nor information on the occurrence of cross-contamination and on-farm feeding errors. However, we do not believe there are significant problems in this regard, based upon the lack of evidence relating to errors associated with other regulated feed ingredients such as antibiotics.

4. If SRMs are prohibited from animal feed, should the list of SRMs be the same list as for human food? What information is available to support having two different lists?

- In our estimation, at least 95% of BSE risk is already eliminated through the existing feed bans based upon conservative compliance estimates. Data indicate the removal of animals that are in the category known as 4-D cattle (dead, down, diseased, disabled) and those condemned at antemortem inspection would remove

the largest percentage of remaining risk. Our data indicate such a step would reduce BSE risk at least an additional 4.1% resulting in a total BSE risk reduction of over 99%. Our estimated cost of taking such a step is approximately $64 to $76 million. If we were to removal of brain and spinal cord from cattle over 30 months this step would reduce risk another 0.8% and at a cost of $1.4-$1.7 million.

5. What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

- We know of no specific method to determine if SRMs had been removed but the NCBA has supported research to develop sensitive methods to detect central nervous tissues material in meat products. Therefore technology might be available for this purpose.

6. If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and material rendered from SRMs?

- We know of no specific method to achieve this marking. Perhaps a food grade dye might be an option.

7. What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

The cost to remove brain and spinal cord from animals over30 months that pass inspection (6.5 million head/year) is estimated to cost $1.4 to $1.7 million based upon industry estimates.

- **Based upon an estimated reduction in risk of 0.80% the Cost/unit of risk reduction could be estimated at $1.75 to $2.1 million based upon industry estimates of cost to remove these tissues.**

If we were to, in addition, remove all remaining SRMs from all cattle over 30 months this would reduce risk by only 0.1% of total remaining risk (the 5% of risk left after existing feed ban compliance).

- Cost to remove from all animal feed production: $130 to $158 million based upon industry estimates.

- **Cost/unit of risk reduction: $1.3 to 1.6 billion**

There is the potential to reduce the economic impact of these changes by allowing the use of meat removed from dead, diseased, disabled (4-D) cattle in pet food. The extent of this reduction in economic impact is uncertain at this time.

- We know of no specific study that has evaluated the environmental impacts of such steps, however, there are individual companies working on alternative disposal and co-generation uses of these material as fuel sources. Perhaps other entities have such information.

8. What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

- We know of no specific study that has evaluated these issues.

9. What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

- We know of no specific study that has evaluated these issues but rather a more common sense perspective that dedicated facilities and equipment would reduce risk by an unknown amount. If SRMs were removed from animal feed it makes sense that the risks posed by cross contamination would be substantially reduced and that such dedicated facilities and procedures might not be necessary. The FDA needs to complete and publish additional risk analysis and cost benefit analysis data relating to these options and their impacts.

10. What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation?

- At this time we know of no specific study that has evaluated these issues.

11. What information, especially scientific data, is available to demonstrate that clean-out would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

- In 1997, FDA stated that the cleanout procedures prescribed in FDA's medicated feed good manufacturing practices (GMPs) were adequate for BSE purposes. Now, FDA is asking whether cleanout would provide adequate protection against cross-contamination if SRMs were to be banned from all animal feed. We do not know if the feed industry has or will be able to analyze the implication of this proposed action within the existing comment period.

12. What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

- This is the first time FDA has asked us this question. Given the large number of poultry slaughtered in the United States, banning avian protein from ruminant feed raises serious economic and environmental issues. We could not identify a data set, nor is there time to develop or to analyze this situation. Prohibiting the use of these ingredients does not seem to make sense from a BSE risk reduction perspective.

13. If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

- This is the first time FDA has asked us this question. We could not identify a data set nor is there time to develop or to analyze this situation. Prohibiting the use of these ingredients does not seem to make sense from a BSE risk reduction perspective. Attempting to reduce risk through removal all ruminant meat and bone meal from all livestock feed in lieu of SRM or other actions to reduce the risk by 5% of the total would cost, based upon industry estimates, $636 million or a cost/unit of risk reduction of $127.2 million. Such a step would be unnecessary if there was an SRM removal option.

14. What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

- This is the first time FDA has asked us this question. We could not identify a data set, nor is there time to fully develop or to analyze this situation. We can say that industry estimates put the cost of removing only the ruminant products at approximately $636 million and the cost of removing avian byproducts would be nearly as much. Therefore, the total cost would likely exceed $1.2 billion. Environmentally sound disposal costs would be on top of these costs. This could easily total over $2.0 billion when all impacts are added together.

15. Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

- There is no "real-world" evidence that these products pose a risk to other species.

16. What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

- There is no evidence that these products pose a risk to cattle, and given the FSIS SRM removal requirements from these products approved for human consumption, if there ever was such a risk it is no longer an issue.

17. If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

- It is unclear what risk poultry litter actually poses to cattle. However, if there is a risk it makes sense that the SRM removal from ruminant byproducts would effectively minimize such risk and render elimination of poultry litter as a feed ingredient unnecessary, if there actually is a significant risk at this time.

18. What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

- We know of no studies at this time that would estimate these costs and we continue to investigate these issues.

19. Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

- It is our understanding that there has never been a situation where tallow produced from animals that died from BSE could transmit BSE under any circumstance and to any class of cattle, such as the most susceptible class the young calf. It seems that as an additional precaution, it is recommended that protein levels be reduced to no more than .15% to further reduce the risk, if any from these products.

20. Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

- We know of no studies at this time that have determined if there are viable options to do this. Perhaps a food grade dye might be an option to mark these products as restricted use.

21. What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?

- We know of no studies at this time that have determined if this is a viable option.

22. What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

- Regarding the economic impact of prohibiting materials from dead stock and non-ambulatory disabled cattle in all animal feed, the National Rendering Association

prepared a study of this question in 2001 but it has not been updated. Our best estimate is that this would cost between $64 and $76 million to remove these products from the animal feed supply.

28. Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?

- Taking such action is absolutely appropriate, and in addition, if BSE risks are further reduced in the U.S. there should be a means to reduce some of the restrictions that are or may be put in place.

29. If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?

- Such an approach would likely require methods to verify either the elimination of the infectious agent, or the initial absence of the agent. Currently this requires incubation studies, but new testing technologies may provide tools so such biological methods would not be necessary.

30. Do FDA's existing authorities under the Federal Food, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in non-ruminant animal feed (e.g., feed for horses, pigs, poultry, etc.) notwithstanding that such materials have not been shown to pose a direct risk to non-ruminant animals? More specifically, under FDA's existing legal authorities, would the potential occurrence of on-farm feeding errors, of cross contamination of ruminant feed with SRMs and other cattle material, or of human exposure to non-ruminant feed (including pet food) provide a basis to ban SRMs and other cattle material from all animal feed?

- We are aware of differing legal opinions some indicate FDA has the existing authority, some indicate they do not. We have not conducted an analysis of the scope of existing legal authorities of the agency nor case law regarding such authority.

31. Are there other, related legal issues on which FDA should focus?

- We are aware of differing legal opinions some indicate FDA has the existing authority, some indicate they do not. We have not conducted an analysis of the scope of existing legal authorities of the agency nor case law regarding such authority.

Summary

The NCBA has and remains completely dedicated to following a science and risk analysis based program to prevent the introduction, amplification and spread of BSE. However, at this time, over 15 years of action, information and analysis indicates that there are no data to support the FDA altering the existing feed regulations.

In addition, even if this situation is altered, as a result of data provided by the expanded BSE surveillance program, a much narrower, defined SRM removal policy (brain and spinal cord only from animals over 30 months that pass antemortem inspection) would be an effective and far more cost effect means to reduce BSE risk. The data show that while the high–risk cattle-derived materials from cattle over 30 months include: the brain, skull, eyes, and spinal cord, portions of the small intestine and tonsils from all cattle, restricting all of these from animal fed is not necessary. The vast majority of the LD-50 doses would be found in brain and spinal cord, likely over 90 of the potentially infectious doses.

Consequently, the discussions relating to SRM removal from animal feeds are only related to the question of if additional measures are needed to further protect animal health. These additional measures would not significantly affect the already incredibly low BSE risk to public health.

The NCBA supports the requirement proposed in January that equipment, facilities, or production lines must be dedicated to non-ruminant animal feeds if they use protein that is prohibited in ruminant feed.

The NCBA supports a process to determine the risks associated with feeding broiler litter, broiler feed and other protein sources of avian or mammalian origin to cattle and FDA action if such an analysis indicates there is a significant BSE amplification and spread risk.

The NCBA supports the FDA in conducting a risk analysis of the use of blood and blood products in cattle diets. If data indicate specific products pose an unacceptable risk then we would support prohibiting the use of those specific products. It appears the data do not support a complete prohibition of the use of all blood products to cattle.

The NCBA also support actions taken in January by the USDA to protect public health and also those announced by the FDA on July 9, 2004 that prohibits the use of cattle-derived materials that can carry the BSE-infectious agent in human foods, including certain meat-based products and dietary supplements, and in cosmetics. These high–risk cattle-derived materials include SRMs that are known to harbor concentrations of the infectious agent for BSE, such as the brain, skull, eyes, and spinal cord of cattle 30 months of age or older, and a portion of the small intestine and tonsils from all cattle, regardless of their age. Prohibited high-risk bovine materials also include material from non-ambulatory disabled cattle, the small intestine of all cattle, material from cattle not inspected and passed for human consumption, and mechanically separated beef. These

measures aid in protecting public health and this leave the discussions contained in the ANPRM as issues related to protecting animal health, but not of direct significance to public health which is fully protected through other, direct means.

Consistent with the basic premise of the Harvard Center for Risk Analysis BSE Risk Analysis, no scientific or other evidence has been provided that would support altering our current FDA feed restrictions at this time. If data indicate there is a need to do so, our analysis of risk reduction steps illustrates that a narrowly defined and targeted SRM removal policy would reduce the majority of risk remaining after that removed by the existing feed restrictions and high rate of compliance.

Last but not least, we strongly encourage the FDA to avoid proposing any changes in the existing fed ban regulations unless the expanded BSE surveillance program provides evidence that such a change is needed based upon risk. In addition, any proposed changes should be subjected to the Harvard Risk Analysis Model to verify they would, indeed reduce BSE risk.

We look forward to FDA responses to the data and information we and others have provided, including another opportunity to participate in a notice and comment rule-making process in the event FDA decides to publish a proposed rule related to this

Respectfully submitted by:

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